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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,486	05/11/2005	Takanori Matsuo	10525.0015-00000	7810

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,486	MATSUO ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/29/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,17-31,34,35 and 38-43* is/are pending in the application.

4a) Of the above claim(s) *1-8,10-12,19-31,34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,15,17,18 and 38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, remarks, and IDS filed 10/29/08 are acknowledged.

2. Claims 1-8, 10-12, 19-31, 34, and 35 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 9, 15, 17, and 18, and newly added Claims 38-43 are under examination.

3. Applicant's amended Title has been entered.

4. In view of Applicant's amendment the previous rejections under the first and second paragraphs of 35 U.S.C. 112, as well as the previous rejection under 35 U.S.C. 101 have been withdrawn. In particular, the amended claims now include method steps and the screening method has been limited to the screening of candidate therapeutics for the treatment of diabetes or renal disease.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 9, 15, 17, and 18, and newly added Claims 38-43 stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,165,733 in view of Ihara et al. (2001).

As set forth previously, The '733 patent teaches a screening method for a therapeutic substance (a mitogenesis inhibitor) comprising cultivating a cell (the contacted cell had to have been "cultivated") and comparing the expression of a gene in the presence or absence of a test compound (see particularly Claims 1 and 2). While the reference does not specifically teach the comparison of mRNA expression of Claim 18, comparisons of gene expression comprise either comparisons of DNA or mRNA expression such that either are readily envisioned as equivalents.

The reference differs from the claimed invention in that it does not teach comparing the expression of a gene encoding the protein of SEQ ID NO:2.

Ihara et al. teaches the protein of SEQ ID NO:2 (TSC-22), is associated with diabetes. In particular, the expression of the gene of SEQ ID NO:1 can be used as a marker for insulin expression. TSC-22 inhibits insulin expression such that a measure

of TSC-22 expression can be used as a measure of insulin expression and the reduction of TSC-22 expression is an indication of increased insulin expression (see the entire Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the screening method of the '733 patent employing the measuring of the expression of the TSC-22 gene of Ihara et al. given the relationship of TSC-22 expression and insulin expression. Said method could be used as a method for screening test substances for their effect on TSC-22 expression as a measure of their efficacy as a therapeutic for the treatment of diabetes.

Applicant's arguments, filed 10/29/08, have been fully considered but are not found persuasive. Applicant argues that in the secondary reference, Ihara et al., the authors found the opposite effect as that described in the instant specification. That is, the authors found that the TSC-22 protein played a suppressive role in insulin gene expression whereas the instant specification describes the TSC-22 protein as being associated with an increase in insulin gene expression.

Regardless of the fact that the reference describes an effect opposite of that described in the instant specification the combined references still provide a reason for assaying the effect of candidate drugs on the TSC-22/insulin pathway. There is no necessity that the motivation or findings of the prior art be identical to that of the instant Inventors.

Applicant asserts that in work subsequent to Ihara et al., i.e., the work of Sugawara et al. (2001) the authors teach away from the earlier finding of Ihara et al.

A review of Sugawara et al. does not support Applicant's assertion. Sugawara flatly states that in previous work, "We found that the expression of TSC-22 gene is increased in the pancreatic islets of an eight-week-old male GK rat, compared to the islets from a control male Wistar rat, in a differential display …. Furthermore, we found that the human insulin gene promoter activity was repressed by the TSC-22 gene product," (page 993). Additional review of the reference reveals that the work concerned the question of whether or not specific SNPs (single nucleotide polymorphisms) correlated with type 2 diabetes. The finding was that they do not. This finding in no way teaches away from the findings of Ihara et al.

7. The following are new grounds for rejection necessitated by Applicant's amendment.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 38 and 42 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a written description rejection for the introduction of new matter into the claims.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method wherein the cell employed in the assay has the ability to produce the protein of SEQ ID NO:2.

Applicant cites multiple pages of the specification in support of the new limitation, however a review of the cites does not disclose an assay employing a cell with this capability.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 38 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the recitation of a cell that produces a salt of the protein of SEQ ID NO:2 is nonsensical as cells do not produce proteins of salts.

12. No claim is allowed.

13. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0841.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/G.R. Ewoldt/
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